K111993 (pg 1/2)

OCT 24 2011

510(k) Summary

Date: June 20, 2011

Applicant/Sponsor: Quantum Medical Concepts, LLC
3518 SE 21st Ave.
Portland, Oregon 97202

Contact Person: Alicia Bach, Office Manager
Quantum Medical Concepts, LLC
PH 503-233-3984
FX 503-233-8541

Proprietary Name: Framewalker 2.0

Common Name: External Fixation System

Classification Name: Class II, 21CFR 888.3030- Single/Multiple component metallic bone fixation appliances and accessories

Product Code: KTT- Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Legally Marketed Devices to Which Substantial Equivalence Is Claimed: The FrameWalker has an identical use and is substantially equivalent to the sole portion of the E-Z Frame External Support Boot, K043289 and the Ace Fischer External Fixation System, K083789. Ref. surgical technique supplied in appendix "B" pg. 15 P/N 880-04-015 'Elevator Attachment'.

Device Description: Framewalker is a "Single Use" walking aid designed to be attached to the foot ring portion of an external ring fixator. The Framewalker is intended for patients who are undergoing procedures requiring ring fixation of the lower extremity. The device is applied to the foot ring portion of a ring fixation frame in order to provide a stable platform below the foot to both protect the bottom of the foot and to allow a patient limited ambulation during treatment as determined by a physician.

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Intended Use: This device is indicated for use in patients who are undergoing external ring fixation of the Foot and Ankle for the following conditions:

For use in the treatment of fracture fixation (open and closed), pseudarthrosis or nonunions of long bones, limb lengthening by distraction, correction of bony or soft tissue deformities and correction of segmental bony or soft tissue defects.

Summary of Technologies: The intended use is identical to the predicate devices shown and the foot platform components are geometrically similar to the EZ-Frame listed in the predicates. The Framewalker incorporates connection methods which are common in size, type and materials to compatible existing ring fixation systems.

Non-Clinical Testing: None Provided.

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 24 2011

Quantum Medical Concepts, LLC
% Alicia Bach
3518 SE 21st Ave.
Portland, OR 97202

Re: K111993
Trade/Device Name: Framewalker
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: October 13, 2011
Received: October 19, 2011

Dear Ms. Bach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111993(pg 1/1)

Device Name: Framewalker

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111993